EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

RAYMOND ALBERT RODRIGUEZ,	§	
	§	
Plaintiff,	§	
v.	§	
	§	Civil Action 4:14-cv-00968
ELI LILLY AND COMPANY;	§	
LILLY USA, LLC; and	§	
JULIA DAWN RAMOS,	§	
	§	
Defendants.	§	

DECLARATION OF JULIA DAWN RAMOS

I, the undersigned, Julia Dawn Ramos, state upon my personal knowledge as follows:

1. I am an adult over age 18 of sound mind and competent to testify as to all matters contained in this declaration. All matters contained in this declaration are based on my personal knowledge.

2. I started employment with Eli Lilly and Company ("Lilly") in January 2002. I am currently employed as a District Sales Manager in Lilly's diabetes business unit and have been in this role since March 1, 2011.

3. Raymond Albert Rodriguez was a diabetes sales representative reporting to me from July 1, 2013 until his termination on October 17, 2013. During that time, Mr. Rodriguez's territory sales partner was a sales representative named Syreeta Barrett.

4. Lilly sales representatives, including Mr. Rodriguez, are subject to various Lilly policies, including the US Policy on Documenting a Sales Call, the U.S. Policy on Business Meals with External Parties, and the U.S. Policy on Promotional Product Samples. True and correct copies of those three policies as in effect during Mr. Rodriguez's time as a sales representative are attached as **Exhibits 1, 2, and 3**, respectively.

5. Because Lilly is a highly-regulated pharmaceutical company and because it takes patient safety very seriously, all sales representatives must follow Lilly's detailed policies regarding promoting pharmaceutical products, expense tracking, and product sample safety, among other policies.

6. One of the diabetes-treatment pharmaceuticals that Lilly manufactures and that Mr. Rodriguez was responsible for promoting was Humalog. Humalog is an insulin product that must be refrigerated. Humalog has a very small temperature window in which it is safe and efficacious. Variations outside the safe temperature range can cause the product to lose effectiveness, which can potentially have safety consequences for a patient.

7. Because of Humalog's temperature sensitivity, Lilly began using a device known as the TempTale monitor as a way to ensure Humalog remained at the appropriate temperature while stored in sales representatives' Lilly-issued refrigerators. The TempTale is a temperature monitor that was rolled out as part of a pilot program at Lilly in April or May 2012. All sales representatives who were part of this trial program—like Mr. Rodriguez—were required to use the TempTale in the Lilly-issued refrigerators sales representatives used to store product samples. Sales representatives with TempTales were required to visually check the TempTale twice daily to determine whether the alarm had been triggered—when it did so, a small bell would appear on the TempTale display. If the alarm triggered, sales representatives were supposed to immediately contact Lilly headquarters for additional instructions and to determine whether Humalog samples were still safe to distribute. Once the alarm triggered, it would remain in alarm status continuously, and the TempTale would need to be replaced.

8. In addition to requiring sales representatives to store Humalog samples in a Lilly-issued refrigerator, Lilly also required sales representatives to transport Humalog samples in a

Lilly-issued cooler to maintain product integrity while transporting the samples. Mr. Rodriguez had two Lilly-issued refrigerators that were housed at a storage facility.

9. On August 31, 2013, Ms. Barrett sent me an unsolicited email expressing a number of concerns about Mr. Rodriguez's sales activities and TempTale monitoring, among other concerns. Because I wanted assistance in addressing Ms. Barrett's email, I forwarded the email to Lilly Human Resources on Tuesday, September 3, 2013, which was the first business day after I received Barrett's August 31, 2013 email.

10. I worked with Lilly Human Resources Consultant Melissa Popa to investigate the allegations of Mr. Rodriguez's policy violations. Ms. Popa asked me to contact Dr. Killam's office to determine whether he was in the office on August 20, 2013. I learned from Dr. Killam's office that he had been out of the office on a two-week vacation at the time Mr. Rodriguez claimed he had a sales call with the doctor. I reported this to Ms. Popa.

11. On October 15, 2013, Ms. Popa and I interviewed Mr. Rodriguez. I was in person with Mr. Rodriguez, and Ms. Popa participated via telephone.

12. Because Ms. Barrett's reports and Mr. Rodriguez's statements were inconsistent as it related to the TempTale, Mr. Rodriguez and I drove to the storage unit where Mr. Rodriguez's Lilly-issued refrigerators were stored to inspect the TempTale monitors.

13. Both TempTale monitors were in alarm status. Using my Lilly laptop, I downloaded the electronic history from the TempTales. The electronic history was later sent to Lilly headquarters for review.

14. After the investigation, Ms. Popa and I concluded that Mr. Rodriguez had violated multiple Lilly policies and that he had committed "misconduct," which is an immediately separable offense.

15. Ms. Popa and I concluded that Mr. Rodriguez falsified a sales call on Dr. Killam by deliberately recording a call on him even though he had not seen him. In reaching this conclusion, we credited Ms. Barrett's description of what had occurred, which was partly corroborated by our investigation (e.g., Ms. Barrett reported that Dr. Killiam was out of the office, and we confirmed that). We also concluded that Mr. Rodriguez was not forthright during the investigation about this sales call. We finally concluded that Ms. Barrett's report that Mr. Rodriguez encouraged her to also falsify a sales call was credible.

16. Ms. Popa and I also concluded that Mr. Rodriguez misreported at least three office lunches because his expense reports did not match the accompanying sign-in sheets, which violated Lilly's Policy on Business Meals with External Parties. We also concluded that Ms. Barrett's report that Mr. Rodriguez encouraged her to similarly ignore Lilly's policy regarding business meals was credible.

17. Ms. Popa and I also concluded that Mr. Rodriguez failed to monitor his TempTale monitors and failed to report TempTale alarms. We also concluded that Mr. Rodriguez either lied to us about checking the monitor every day or lied about the alarms not being triggered. We further concluded that Ms. Barrett's report that Mr. Rodriguez encouraged her to similarly ignore TempTale monitors credible.

18. Mr. Rodriguez's alleged disability and alleged request for a leave of absence were not factors in the decision to terminate his employment.

19. I have no knowledge that Mr. Rodriguez has ever complained of or otherwise reported discriminatory conduct.

20. Mr. Rodriguez was discharged due to his serious misconduct described in Paragraphs 15, 16, and 17.

21. Based on my experience with Lilly, including as a sales representative and a District Sales Manager, I am not aware of any employee who has been found to have committed the violations Mr. Rodriguez committed but was not discharged.

22. When Mr. Rodriguez mentioned an appointment to me in October 2013, I directed him to Employee Health Services, and I told him to take the time he needed to make sure he was healthy and ready to deal with the sales duties.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 13, 2015.

Julia Dawn Ramos

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Declaration of Julia Dawn Ramos

Exhibit 1

Lilly
Answers That Matter.

US Policy on Documenting a Sales Call

Policy Statement – Employees must comply with all applicable laws, regulations, government or court orders or decrees, and company policies regarding documenting a sales call between sales personnel and an appropriate Health Care Provider.

Business Need – To set forth a policy and procedures regarding documenting a sales call between sales personnel and appropriate Health Care Providers to foster compliance with all applicable laws, regulations, government or court orders or decrees, and company policies.

Scope – This policy applies to all US-based employees who are required to record sales calls.

Definitions – Click here for definitions of the following terms: External Party, Health Care Provider (HCP), Licensed Prescriber, Promotional Materials, Sales Personnel, Sample.

General Information

- A sales call is a face-to-face interaction that meets both of the following criteria:
  - Is between a Lilly sales representative and an appropriate HCP customer (i.e., a licensed prescriber meeting brand-approved territory-to-physician (TTP) rules or a non-prescribing HCP who is involved in patient care, as designated by local leadership).
  - Includes a dialogue involving one or more of the following approved topics: Lilly product(s), associated solutions, appropriate brand patient(s), appropriate disease state(s).
- The purpose of a sales call is to provide an appropriate HCP customer with approved information related to Lilly product(s), associated solutions, appropriate brand patient(s), and/or appropriate disease state(s) to allow the HCP customer to choose the best therapy for the HCP customer's patients.
- The following activities are not considered a sales call:
  - Dropping off promotional material and/or Lilly samples without having a discussion with an appropriate HCP customer.
  - Speaking only with an individual who is not an appropriate HCP customer.
  - Phone call with an appropriate HCP customer.
  - Social or personal interaction with an appropriate HCP customer.
  - Written correspondence with an appropriate HCP customer.

    NOTE: Any written communication from sales personnel containing a (brand or generic) product name/therapeutic class or a disease state is considered promotional and must be approved through the Promotional Materials Approval Process. (See the US Policy on Promotional Materials.)

Call Notes

- For each sales call, the sales representative must accurately document the interaction in an approved sales call recording system (e.g., Structured Call Note (SCN)) or other documentation system approved by the appropriate business unit.
  - A "call" will be credited only for appropriate interactions with appropriate HCP customers.
- A sales representative should not record any information regarding an appropriate HCP customer's statements, questions, or actions during a sales call outside of an approved sales call recording system. However, if it is absolutely necessary to create any other records (e.g., personal logs), the sales representative is personally accountable for complying with the company document retention policy and must submit these records to corporate upon request.

Handling Confidential Information

- Sales personnel are provided with confidential company information to use only for legitimate business purposes. This information includes sales and marketing strategies, Lilly personnel and customer information, resource allocations, and information from the Premier system, including data from IMS Health (e.g., prescription, Arrow and DDD data).
- In compliance with the Global Policy on Company and External Party Information Assets, employees must take precautions to avoid disclosing company confidential information, intentionally or unintentionally, to unauthorized third parties unless prior legal approval has been obtained. Employees may share confidential company information only with other Lilly personnel or authorized third parties (e.g., joint venture partners) who need the information to successfully conduct Lilly business.
- Employees must retain confidential company information according to company record retention policies.
- Employees must comply with all confidentiality obligations regarding IMS Health data. Employees must not, under any circumstances, disclose or discuss the data with anyone except other Lilly employees, IMS Health, or third parties for whom IMS Health has granted written permission for such disclosure. Employees must not share IMS data with any external party.
- Employees must respect and abide by the wishes of any HCP who asks that his/her prescriber data not be made available to company sales representatives. (For more information, contact the Director of Business Reporting.)

Policy Owner & Contact:	Click here
Policy Effective Date:	18 May 2010
Last Reviewed Date:	April 2010
Version:	2.0

NOTE: If you are using a printed copy of this document, verify that the version number is consistent with the current version available at the Ethics and Compliance LillyNet site

Rodriguez v. Eli Lilly and Company, *et al.*

Declaration of Julia Dawn Ramos

Exhibit 2

Lilly
Answers That Matter.

U.S. Policy on Business Meals with External Parties

Policy Statement – Employees must comply with all applicable laws, regulations, government or court orders or decrees, and company policies regarding business meals with External Parties. Business meals shall never be based on or linked to any prescribing, access, Formulary Status, purchasing, or reimbursement policies or practices of any Health Care Provider or any other External Party. Lilly supports and adheres to the AMA Guidelines on Gifts to Physicians and the PhRMA Code on Interactions with Healthcare Professionals.

Business Need – To set forth a policy and procedures regarding business meals with External Parties to foster compliance with all applicable laws, regulations, government or court orders or decrees, and company policies.

Scope - This policy applies to all U.S.-based employees who participate in business meals with External Parties.

- The following types of meals are out of scope: (1) meals that are attended only by Lilly employees, Lilly vendors/suppliers, and/or Lilly alliance partners (see the U.S. Policy on Travel and Expense Reporting); (2) meals between a Lilly employee and an External Party with whom the employee has a personal relationship when the primary purpose of the meal is not business related and the meal is not on company time or paid for by the company.

Definitions – Advisory Board, Consultant Task Force, External Party, FDA-Regulated Program, Feedback Activity, Formulary Status, Health Care Provider (HCP), Investigator, Medical Conference, Non-HCP Advocate, Non-HCP Executive, Non-HCP Policymaker, Thought Leader, Value-Based Decision Maker.

Background Information

- The value of business meals, among other transfers of value, provided to teaching hospitals and physicians who have an active medical license must be publicly disclosed as part of Lilly's Corporate Integrity Agreement and/or the Sunshine provisions of the Patient Protection and Affordable Care Act (PPACA). In addition, in certain states, Lilly is also required to disclose the value of business meals, among other things, provided to physicians and additional covered recipients (both individuals and institutions, as defined by each state). Accurate reporting of business meals is critical for Lilly to meet these external disclosure obligations.
  - For more information on reporting requirements, see the state compliance reporting collaboration site and the physician payment reporting collaboration site.
- Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide HCPs with valuable scientific and clinical information about medicines that may lead to improved patient care.
- In order to provide important scientific information and to respect HCPs' abilities to manage their schedules and provide patient care, company representatives may occasionally provide meals as a business courtesy to the HCPs as well as members of their staff attending presentations, so long as the presentations comply with this policy.

- Occasional modest meals may also be offered to non-HCP External Parties during discussions about Lilly business.

General Provisions

- Unless otherwise provided in this policy, the provisions of this section apply to all business meals with External Parties, both HCPs and non-HCPs.

Compliance with Laws and Office/Institutional Requirements

- All business meals (and, where allowed, entertainment) must comply with any applicable laws or office/institutional requirements regarding the provision of items of value to HCPs or other External Parties. If those external requirements conflict with any provision of this policy, the more restrictive provisions apply.
- Meals or other events (e.g., receptions) at a Medical Conference must comply with the rules of the organization sponsoring the Medical Conference.

Frequency

- Meals may be provided on an occasional basis only.

Venue

- The venue of a business meal must be conducive to business discussions.
- Venue is limited to restaurants, hotels, conference rooms, External Party offices/institutions, and Lilly facilities.
    - Examples of unacceptable venues include, but are not limited to: (1) any entertainment venue (e.g., golf courses, amusement parks, dinner cruises); (2) any location which may be perceived as lavish based on local standards; and (3) the home of the Lilly employee or External Party.
    - See Appendix A, Managed Healthcare Services Meals with Non-HCP Executives and Appendix B, Corporate Affairs Meals and Entertainment with Non-HCP Policymakers and Non-HCP Advocates for limited exceptions. See also the U.S. Policy on Executive Partnership Program.
- Special rules for field sales personnel (i.e., U.S.-based sales representatives and district sales managers)
    - Field sales personnel may provide meals to an HCP only in the following situations: (1) in the HCP's office/institution; or (2) at an FDA-Regulated Program where the speaker and the participants are able to interact (i.e., Face-to-Face or remote live, but not DVD playback).
    - Field sales personnel may attend, but not pay for, meals with an HCP only in the following situations:
        - Meals with the following types of contracted HCPs who are on overnight status:
            - A speaker, if meeting to prepare for a scheduled speaker program
            - Attendees at speaker training or a Feedback Activity, if the field sales personnel has been approved to attend
            - A presenter at a Lilly meeting

- At a pre-planned meal or reception at a Medical Conference (1) that is planned by an internal Lilly department or the organization sponsoring the Medical Conference, and (2) where any direct costs to Lilly are paid for by an internal cost center
- At a meal sponsored by the Lilly Grant Office (LGO), if allowed by the LGO

Value

- The value of a business meal (i.e., what the External Party would pay for the meal if he/she purchased it on the open market, regardless of the price actually paid by Lilly) must be modest based on local standards.
  - For meals in conjunction with meetings planned by Global Travel and Meeting Services (GTMS), see the U.S. Procedure on Meetings.
  - For all other business meals, the recommended value (per person) of a business meal or reception in the U.S. will be set as a flag in EERS. These flags are as follows: (1) Snack or in-office meal: $25/person; (2) Breakfast: $35/person; (3) Lunch: $35/person; and (4) Dinner: $100/person.

    NOTE: It is expected that nearly all business meals will be below the recommended flags. However, Lilly recognizes that occasionally circumstances result in a meal's value exceeding these recommendations. In all situations, the actual value of the meal must be reported. Supervisors are responsible for understanding and approving exceptions and providing appropriate coaching.
- Costs that must be included in a meal's value: food, beverages, tip, taxes, delivery fees, transportation, parking, and deposits. (If drinks and/or a reception are provided immediately before or after a meal, the cost of the drinks/reception must be included in the meal's value.)
- Costs that are not included: audio/visual equipment rental fees, facility rental fees, speaker fees, and security fees.

Attendees

- The total number of attendees must allow adequate opportunity for product or business discussion.
  - All attendees at a business meal, including office staff, must be appropriate for participation in the accompanying presentation. Appropriate participants would be those whose roles and responsibilities allow them to have a meaningful discussion concerning our products or other business and whose attendance would directly benefit patient care.
- Directors and staff of a Medicaid or mental health department must be considered HCPs.
- There may be no more than seven (7) external HCPs in attendance at a business meal, regardless of the number of Lilly attendees, except in the following situations: (1) meals with individuals under contract to Lilly; (2) meals in the office/institution of an attending External Party; (3) meals at Lilly; (4) speaker program meals; (5) pre-planned meals/events at a Medical Conference; (6) meals hosted by Medical Personnel with Thought Leaders and/or Value-Based Decision Makers (VBDMs) (and/or their faculty members) who have previously expressed an interest in meeting with Medical Personnel; or (7) meals with HCPs from outside the U.S.
- For meals with individuals under contract to Lilly, only External Parties who are currently under contract for the relevant activity (e.g., Advisory Board, Consultant Task Force, clinical study, speaker training) may attend.
- Spouses/other guests of External Parties may not be invited to a business meal.
- If a spouse/other guest arrives with an invited External Party, the spouse/guest must be asked to leave unless one of the following situations exists:

- For meals with individuals under contract to Lilly and pre-planned Medical Conference meals/events, the External Party has arranged in advance to pay for the cost of the spouse/other guest's meal.
- For FDA-Regulated Programs, the spouse/guest is an HCP for whom the information to be presented is relevant to his/her practice or meets any other criteria that the marketing team (or other internal team utilizing a speaker) has established for appropriate attendees.
- For all other meals, (1) the spouse/guest is an HCP, Non-HCP Policymaker, or Non-HCP Advocate in a field relevant to the information to be discussed at the meal; and (2) allowing the spouse/guest to stay will not cause any applicable attendee limit to be exceeded.

- If invited by Medical Personnel, non-sales personnel may attend meals hosted by Medical Personnel with Investigators from a specific study, currently contracted advisors or consultants, Thought Leaders, or VBDMs to listen to, but not participate in, the discussion.

Transportation

- Employees may: (1) transport External Parties to/from a business meal in a company car; (2) pay for transportation to/from a business meal via taxi; or (3) arrange for local group transportation to/from a business meal.
  - Group transportation must be arranged through Global Travel and Meeting Services.

Expense Reporting

- All expenses for meals must be recorded consistent with the U.S. Policy on Travel and Expense Reporting and U.S. Procedure on Travel and Expense Reporting.
- Employees may not share expenses with Lilly alliance partner personnel for an individual business meal with an External Party.

Prohibitions

- The following are prohibited (unless allowed under Appendix A or Appendix B):
  - Entertainment (e.g., sporting events, theater productions, concerts, comedians, background musicians).
  - Providing any of the following: (1) meals and/or entertainment in a manner inconsistent with this policy with personal funds, even if reimbursement from Lilly is not requested; (2) meals in cash or in cash equivalents (e.g., gift certificates for restaurant meals, meal vouchers); (3) homemade food items; or (4) alcohol in conjunction with transportation to/from a business meal (or, where allowed, entertainment activity).
  - Bringing either of the following into an External Party's office/institution: (1) appliances to prepare food; or alcohol.

Policy Effective Date:	01 January 2009
Version Effective Date:	01 October 2012
Last Reviewed Date:	September 2012
Version:	3.0

NOTE: If you are using a printed copy of this document, verify that the version number is consistent with the current version available at the Ethics and Compliance LillyNet site.

Appendix A
Managed Healthcare Services Meals with Non-HCP Executives

- If approved and implemented as outlined below, Managed Healthcare Services (MHS) personnel may host meals with approved Non-HCP Executives at the home of the Lilly employee or External Party. These meals may be catered or homemade.

Authorization of Individuals

- In order for MHS personnel to host meals under this appendix, the Non-HCP Executive must be individually authorized as described in this section.
    - In some circumstances, meetings of multiple External Parties (e.g., association meetings, industry advisory boards conducted by someone other than Lilly at which Lilly may participate) may be approved. If a group meeting is approved, individual interactions with the participants at the meeting do not need to be separately approved.
- A request to authorize an External Party as a Non-HCP Executive must be submitted to MHS Operations via a completed Non-HCP Business Meals and Entertainment Authorization Form.
- The Vice President of MHS and Puerto Rico (or his/her designee) is the final approver for any request to authorize an individual as a Non-HCP Executive. An individual may not be approved unless he/she meets the definition of a Non-HCP Executive.
- If authorization of an individual as a Non-HCP Executive is granted, that authorization (1) must include the specific employees (by name or title) who may interact with the Non-HCP Executive and (2) is valid until change of role/position/job responsibilities of the individual (either the Non-HCP Executive or an authorized Lilly individual).
- MHS Operations must maintain an up-to-date list of all authorizations, both Non-HCP Executives and corresponding employees.

Provision of Business Meals to Authorized Non-HCP Executives

- Business meals with an authorized Non-HCP Executive must take place in a context that is conducive to business interaction.
- There may be no more than five (5) employees present for each authorized Non-HCP Executive.
    - All employees in attendance must have been authorized to interact with the Non-HCP Executive.
    - If there are multiple Non-HCP Executives at an event, at least one Lilly person must be present with each group of authorized Non-HCP Executives.
- The spouse/other guest of an authorized Non-HCP Executive may attend if the meal is at a strictly Lilly-sponsored event or in conjunction with a non-Lilly organized convention or a meeting where spouses normally attend (e.g., a dinner at a trade association meeting).
- The spouse/other guest of an authorized Lilly individual may attend if prior authorized in accordance with the U.S. Policy on Travel and Expense Reporting and U.S. Procedure on Travel and Expense Reporting. This approval must be completed for each event.
- If any unauthorized persons are in attendance at a business meal with an authorized Non-HCP Executive, the meal does not qualify under this appendix.

Appendix B
Corporate Affairs Meals with Non-HCP Policymakers and Non-HCP Advocates

Business Meals with Non-HCP Policymakers and Non-HCP Advocates

- If there are no HCPs in attendance, meals provided by Corporate Affairs personnel to Non-HCP Policymakers and Non-HCP Advocates may take place at the home of the Lilly employee or External Party. These meals may be catered or homemade.
- There is no limit on the number of Non-HCP Policymakers or Non-HCP Advocates who may be invited to a business meal.
- Spouses/other guests of Non-HCP Policymakers and Non-HCP Advocates may be invited to business meals.

Modest Entertainment with Non-HCP Policymakers

- Business meals with Non-HCP Policymakers may take place at an entertainment venue.
- Modest entertainment may be provided to Non-HCP Policymakers and may take place at an entertainment venue.
    - If any entertainment is provided, it must be held in conjunction with a Lilly meeting and must be incidental to the main purpose of the meeting.
- There is no limit on the number of Non-HCP Policymakers who may be invited to a modest entertainment event.
- Spouses/other guests of Non-HCP Policymakers may be invited to modest entertainment events.

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Declaration of Julia Dawn Ramos

Exhibit 3

U.S. Policy on Promotional Product Samples

Policy Statement – Employees must comply with all applicable laws, regulations, government or court orders or decrees, and company policies regarding Samples, including the regulations under the Prescription Drug Marketing Act (PDMA), concerning the obligation to control and audit Sample distributions and investigate any potential falsification, diversion, significant loss, or improper distribution of legend pharmaceutical Samples distributed by Eli Lilly and Company. In addition, employees must comply with the PDMA provisions requiring the reporting of all falsifications, thefts, significant unaccountable losses, and any convictions under the PDMA involving its employees. Employees must comply with the Patient Protection and Affordable Care Act (PPACA) provisions requiring the tracking and reporting of product Sample requests and distributions.

Business Need – To set forth a policy and procedures regarding Samples to foster compliance with all applicable laws, regulations, government or court orders or decrees, and company policies.

Scope – This policy applies to all U.S.-based employees who distribute Samples.

Definitions – Health Care Provider (HCP), Institutional Pharmacy, Licensed Prescriber, Lot Number, Prescription Drug Marketing Act (PDMA), Retail Pharmacy, Sample, Territory-To-Physician (TTP) Rules.

General Provisions

- For more detailed information on the requirements in this policy, see the U.S. Samples Reference Tool.
- When required to contact Sample Compliance and Accountability, use the following telephone number: 1-800-222-INDY.
- Sales representatives must document Sample transactions described in this policy in the Sales Force Automation Tool.
- Sales representatives must maintain their copy of documentation relating to requests, receipts, forms, reports, and records related to Samples for a minimum of three (3) years and must maintain this documentation so that it is readily retrievable within two (2) business days.

Use of Samples

- A Sample is intended for use by a Licensed Prescriber to initiate a patient on therapy in order to assess the efficacy and/or tolerability of the drug.
- A sales representative may distribute Samples only (1) in amounts that he/she determines are reasonable for the Licensed Prescriber's practice based on the Licensed Prescriber's practice size and prescribing patterns and (2) consistent with product labeling.

- Samples must not be:
  - Traded, sold, bartered for, returned for credit, or submitted to any public or private third-party payer (e.g., Medicaid, Medicare, private insurers, or other third parties) for reimbursement.
  - Distributed to:
    - A Retail Pharmacy, whether at the request of a Licensed Prescriber or otherwise.
    - A commercial wholesaler, whether at the request of a Licensed Prescriber or otherwise.
    - A person who is not a Licensed Prescriber.
  - Distributed at conventions, hospital displays, or symposia.
  - Provided to a Licensed Prescriber knowing that the Sample would be used:
    - For long-term maintenance therapy.
    - As a program to reduce costs.
    - By the prescriber and/or his/her family members.
- A sales representative must notify Sample Compliance and Accountability if he/she becomes aware of any HCP charging a dispensing or storage fee for Samples.

Sampling Process

Ordering Samples

- Only sales representatives who have successfully completed all required Sample training may order and distribute Samples.
- Sales representatives must keep the following addresses current in Lilly Net:
  - Permanent residence
  - If different than permanent residence:
    - Mailing address
    - Shipping address for refrigerated Samples

      NOTE: Refrigerated Samples must be shipped only to the sales representative's home address, or to a UPS Store for pickup.
    - Shipping address for non-refrigerated Samples
    - Sample storage address

  NOTE: After updating a shipping address, a sales representative should allow three (3) business days before ordering Samples to be delivered to that address to allow time for the address to be updated.

Receiving Samples

- For a new sales representative, sales representative with a new sampling assignment, or sales representative who has moved his/her storage location, a Sample Storage Requirements Form must be completed by the sales representative, signed by the sales representative and sales management or independent vendor, and received by Sample Compliance and Accountability prior to the initial shipment of any Samples by the sales representative.
- The sales representative or his/her proxy (i.e., a person 18 years of age or older) must sign for Sample delivery. The sales representative is responsible for decisions made by the proxy.
  - The proxy may sign to accept the shipped packages from the shipper.
  - The proxy may not distribute Samples.
  - The Sample shipment is not considered "received" until the sales representative enters the required information into the Sales Force Automation Tool.
  - The sales representative is responsible for all boxes for which a signature was obtained.
- A sales representative receiving refrigerated Samples from the UPS Store must pick them up and place them in his/her Lilly-issued refrigerator on the same day that the UPS Store informs him/her that the Samples are available. In addition, the sales representative must verify that the package was shipped from a Lilly distribution center either that same day or the previous day.

  NOTE: If either of these conditions is not met, the sales representative must not accept the shipment.
- A sales representative must verify that the contents of the shipment are accurate, complete, and not damaged. The sales representative must verify that the products he/she receives are product Samples and not trade product.

Storing Samples

- Sales representatives are responsible for storing Samples in a manner that maintains product stability, integrity, and effectiveness (e.g., in accordance with the product's labeled storage conditions); keeps Samples free of contamination, deterioration, and adulteration; and protects against theft.
  - Samples and Sample refrigerators containing Samples must not be stored in garages.
- Sales representatives must store Samples requiring refrigeration in a company-provided refrigerator.
  - Sales representatives must:
    - Keep the refrigerator on a level surface.
    - Clean dirty condenser coils, if applicable.

- Check the seals on the refrigerator door and inspect for wear. If wear is identified, the sales representative must replace the refrigerator with new company-provided refrigerator.

- Sales representatives must make the Sample storage location available for inspection.
- If a sales representative becomes aware of any situation that may have impacted the quality or integrity of a Sample (e.g., prolonged exposure to temperatures outside the labeling requirements, power outage, flooding, damage to the packaging), the sales representative:
  - Must segregate the potentially impacted Samples from any non-impacted Samples;
  - Must not distribute or reallocate the Samples; and
  - Must contact Sample Compliance and Accountability for instructions within one (1) business day.

Transporting Samples

- Sales representatives are responsible for transporting Samples in a manner that maintains product stability, integrity, and effectiveness (e.g., in accordance with the product's labeled storage conditions); keeps the Samples free of contamination, deterioration, and adulteration; and protects against theft.
- Samples with the earliest expiration date should be distributed first. Expired Samples must not be distributed.
- Samples are to be transported in a company-approved vehicle.
- Samples transported in a vehicle:
  - Must not be left in open view (e.g., Sample packaging should not be visible through window).
  - Must be removed from the vehicle when the vehicle is used for personal use (e.g., holidays, vacation day, weekends).
- For refrigerated products, Samples must be transported in a company-provided cooler. Refrigerated Samples must be removed from the cooler at the end of each working day and stored in a company-provided refrigerator.

Verifying Eligible Prescribers

- A sales representative must distribute Samples only to Licensed Prescribers authorized to prescribe such drugs and only upon obtaining the Licensed Prescriber's written request.
- A sales representative must verify a Licensed Prescriber's state license eligibility in the Sales Force Automation Tool each time prior to leaving any Samples.
  - A sales representative must not leave Samples if the Licensed Prescriber's eligibility is listed as Ineligible, Unknown, or Blank.
- Licensed Prescribers identified for sampling must be consistent with brand strategy, (i.e., Territory-To-Physician (TTP) rules), and all promotion to them must be consistent with product labeling.

Distributing Samples

- Following a request for Samples from a Licensed Prescriber, the sales representative must prepare a sample card completely and legibly.
  - Sample card must include:
    - Name of Licensed Prescriber
    - Address of Licensed Prescriber
    - Professional title of Licensed Prescriber
    - Signature of Licensed Prescriber
    - State license number (DEA if applicable) of Licensed Prescriber
    - Name of product
    - Strength of product
    - Quantity requested and received by Licensed Prescriber
    - Name of manufacturer and authorized distributor of record (dist. may not be applicable)
    - Date of request/receipt

    NOTE: This information must be accurate to meet Sample regulations.
  - Sample cards must be completed using blue or black indelible ink.
- The Licensed Prescriber whose name appears on the sample card must sign and date the sample card acknowledging the request/receipt of the Samples.
  - The sales representative must make every attempt to witness the signature of the Licensed Prescriber on the sample card.
- If a sales representative determines that there is a discrepancy between the Samples recorded on any sample card and the amount that was actually distributed, the sales representative must return to the Licensed Prescriber and obtain an acknowledgement (e.g., dated initials or signature) from the Licensed Prescriber.
- The sales representative must distribute a package insert with all Sample deliveries.

  NOTE: Package inserts are provided with each Sample unit. If a multiple-unit Sample package (e.g., Humalog cartridge, 1x5 cartridge) is distributed in a partial quantity (e.g., two cartridges from a package of five), a package insert must be provided with the partial quantity.
- Standing or open-ended requests for Samples from Licensed Prescribers are not permitted. A separate written request is required for each drug Sample or group of Samples.
- The sales representative must document the identity (i.e., product name, code, strength, package size), quantity, and Lot Numbers of all Samples distributed to the Licensed Prescriber.
- The sales representative must mail the original sample card to Sample Compliance and Accountability for record retention.

- The original sample card must be mailed in time for it to be received by Sample Compliance and Accountability within 30 calendar days from the call date.

- Sample cards may be returned to the sales representative from Sample Compliance and Accountability due to incomplete or illegible information. If a sample card is returned, the sales representative must:
  - Follow the instructions received with the returned card for completing an incomplete sample card or for creating a replacement sample card.
  - Return the sample card for processing as requested.
- For distribution to institutional pharmacies:
  - A sales representative may distribute Samples to an Institutional Pharmacy only at the request of a Licensed Prescriber.
  - In addition to the requirements for request and receipt above, the sample card for Samples distributed to an Institutional Pharmacy must contain:
    - The name and address of the Institutional Pharmacy to which the Sample is to be delivered.
    - The printed full name and professional designation of the person receiving the Sample at the Institutional Pharmacy.
    - The signature of the requesting Licensed Prescriber and the person receiving the Sample at the Institutional Pharmacy.
- To request a direct shipment of Samples to a Licensed Prescriber:
  - A sales representative must obtain a Direct Shipment Form.
    - The Direct Shipment Form must contain the same information as the sample card.
  - Obtain the Licensed Prescriber's signature and date on the completed form.

Sample Reallocation

- The "giving" sales representative must obtain an approval code from Sample Compliance and Accountability prior to reallocating.
- A sales representative may reallocate Samples only to other Lilly sampling sales representatives who promote that product.
- Samples must not be reallocated to alliance partner representatives or contract sales organizations.
- Sales representatives must not ship refrigerated Samples as part of a reallocation. Reallocated refrigerated Samples must be delivered in person.
- The "giving" sales representative must not reallocate Samples there were not stored per the storage conditions on the label.

Sample Returns

- Samples must be returned to Indianapolis if:
  - They are outdated, damaged, recovered after a theft, or recalled.

- The sales representative is instructed by Sample Compliance and Accountability to return the Samples.

- The sales representative returning Samples must call Sample Compliance and Accountability for instructions before returning the Samples.
- Sales representatives must never discard Samples.
- A sales representative must not remove Samples from a Licensed Prescriber's office.

Thefts and Losses

- If a Sample is lost, within 24 hours after becoming aware of the loss, a sales representative must notify the following:
  - Sales representative's management
  - Sample Compliance and Accountability
- If a Sample is stolen, within 24 hours after becoming aware of the theft, a sales representative must notify the following:
  - Sales representative's management
  - Sample Compliance and Accountability
  - Local law enforcement
    - If it is a theft, the sales representative must contact local law enforcement to report the incident and request a copy of the police report for submission to Sample Compliance and Accountability.
- If stolen or lost Samples are recovered, the sales representative must notify Sample Compliance and Accountability. If the discovery is made after hours, on a weekend, or on a holiday, the sales representative must contact Corporate Security at 317-276-3351.
  - Recovered Samples cannot be distributed and must be returned per the returns instructions discussed in this policy.

Physical Inventory Counts

- A sales representative must conduct a monthly physical inventory count.
- The sales representative will enter the physical inventory count in the Sales Force Automation Tool.
- An independent inventory contractor will conduct a complete physical inventory of Samples in a sales representative's possession and inspect the Sample storage site at least once annually (rolling 12 months) for each sales representative who distributes Samples.
- A "For Cause" inventory may be conducted if there is reason to believe that a sales representative's Sample practices may not be in compliance with this policy.
  - "For Cause" inventories are to be performed by an independent inventory contractor or designated Lilly personnel.
- Sales management may request and conduct an inventory at any time.

Final Close Out

- Sales managers are responsible for physically closing out Samples for those sales representatives who are exiting the company, transferring to non-sampling assignments, or taking any leave of absence that exceeds 90 days.

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NOTE: If you are using a printed copy of this document, verify that the version number is consistent with the current version available at the Ethics and Compliance LillyNet site.